REMARKS

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 29 and 31-33 are pending in the application, with claim 29 being the independent claim. Claims 1-28 and 30 have been canceled without prejudice and Applicants reserve the right to file said claims in another application. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based upon the above Amendment and the following Remarks, the Applicants respectfully request the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Specification:

The Examiner has asserted that the amendments made to the specification submitted on December 20, 2004, do not comply with the 37 C.F.R. §1.121. Applicants herewith submit a new amendment to the specification complying with the requirements of 37 C.F.R. §1.121.

Therefore, Applicants respectfully request this objection be withdrawn.

Rejection under 35 U.S.C. §112, 2nd paragraph:

Claims 29 and 31-33 stand rejected under 35 U.S.C. §112, 2nd paragraph, because the terms "immunotype," "from multiple donors," and "HS cells that are homozygous for the Major Histocompatibility Complex haplotypes" are vague and indefinite. The Examiner also asserts that claim 29 is vague and indefinite because "according to the teaching of the specification, the claimed HS cell depository contains various stem cell lines from multiple donors, each donor may have a MHC haplotype that is distinct from others, yet the claim reads on a cell depository

wherein all of the HS cells are homozygous for a MHC haplotype." Further, the Examiner asserts that there is insufficient antecedent basis for the limitation "the Major Histocompatibility Complex haplotypes" of claim 29. The Examiner is thanked for her attention to this detail.

Applicants have amended the claims to overcome the Examiner's rejections. As such, Applicants respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. §112, 1st paragraph:

The claimed invention is enabled by the specification, such that one of ordinary skill in the art would know how to use the claimed invention without undue experimentation.

Claims 29, and 31-33 stand rejected under 35 U.S.C. §112, 1st paragraph, because "the specification, while being enabling for making a mouse HS cell line via mitotically activating non-fertilized female post-meiosis I diploid germ cells with ionomycin and DMAP, does not reasonably provide enablement for making a human HS cell line or making a non-human mammalian HS cell line via any type of mitotic activation, and it does not reasonably provide enablement for using the mammalian embryonic stem (ES) cell lines for therapeutic transplantation."

Applicants respectfully traverse this rejection for at least the following reasons. First, the claims as currently amended set forth a specific activation method and are supported, for example, by the specification at page 45. The Examiner cites Mitalipov et al. and Newman-Smith, et al. for the premise that many factors may influence the mitotic capability of parthenotes from which pluripotent stem cells could be obtained. The instant specification not only discloses methods for activating mouse oocytes to yield mouse embryonic stem cell lines, but also methods for activating human oocytes to yield human homozygous stem cells. The activation

methods disclosed in the references cited by the Examiner are different from those specifically set forth in the instant specification. Therefore, the claims as amended are enabled by the specification.

Second, the Examiner cites Gearhart et al. and Liu et al. to show that the therapeutic potential of establishing an embryonic stem cell bank and the vision of obtaining homozygous stem cells from parthenogenetic ES cells are known in the art. The Examiner continues on to state that "however, establishing human ES lines from parthenogenetic ES cells has not become practical in the art at the time of instant priority date, and has not become routine after the filing date of instant application." Office Action, p. 7.

For this premise the Examiner cites an article by the inventors that states, "so far, further culturing of the [human] inner cell mass produced by the activation method has not been successful" Lin et al., Stem Cells 2003; 21:152-161 (page 158). However, the Examiner has taken this quote out of context. The entire section that includes this quote discusses various methods of activation and their respective outcomes. The claims as amended set forth the activation method of sham ICSI followed by calcium ionophore, which the article indicates, "one [oocyte] developed to a late blastocyst and, after assisted hatching and further culture, gave rise to proliferating cells that survived more than two passages." Lin et al., p. 158. This reference also sets forth that the cells derived from the activation method were cultured "on mitotically inactivated feeder derived from mouse embryonic cells that survived beyond two passages." (p. 160). The specification sets forth culturing techniques at pages 33 and 44-45.

The Examiner also cites several references for the premise that others have experienced a barrier in culturing ES cells. See Gearhart, Mitalipov et al., Newman-Smith et al., and Taylor et al. However, the references cited by the Examiner use different activation methods and not the

sham ICSI and calcium ionophore set forth in the claimed invention. Further, the Lin et al. reference shows proliferating cells created from parthenogenetically activated human oocytes. See Figure 5.

Finally, the Examiner asserts that "the intended use of the ES cell bank is drawn to providing human ES cells for therapeutic transplantation using the ES cell depository to prevent host immune rejection: [and that] neither prior art of record nor the specification provides adequate disclosure to show such cells could indeed be used in human stem cell therapy." Office Action, p. 9. The Examiner cites several references to support the assertion that there are challenges to using stem cells. This argument by the Examiner is improper; the Applicants do not claim an intended use, but rather a method of creating a cell depository.

Therefore, the Applicants have enabled the method for creating a HS cell depository created by the activation method set forth in the claims that are pluripotent and homozygous with respect to MHC haplotypes. As such, this rejection should be withdrawn.

Rejection under 35 U.S.C. §103:

The cited prior art does not teach each and every element of the claims, specifically the activation method of sham ICSI and calcium ionophore.

Claims 29, and 31-33 stand rejected under 35 U.S.C. §103, as being unpatentable over Gearhart (Science 1998; 282:1061-2), in view of Liu et al. (Acta Zoologica Sinica 1998; 44:247-8), Stice et al. (U.S. 6,235,970), and Ohnuma et al. (J. Hematother Stem Cell Res 2000; 9:541-550).

Applicants respectfully traverse this rejection. Based upon the amendments set forth in this response, the cited references do not teach each and every element of the claimed invention,

namely the recited activation method of sham ICSI and calcium ionophore. As such, the references do not establish a prima facie case of obviousness and this rejection is moot and should be withdrawn.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request(s) that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Respectfully submitted,

REED SMITH, LLP

Date: 10/20/05

By: _____
Toni-Junell Herbert
Reg. No. 34,348

1301 K Street, N.W.
Suite 1100 – East Tower
Washington, DC 20005
(202) 414-9200